

### **REMARKS**

The courtesies extended by Examiners Sandra Wegert and Elizabeth Kemmerer to applicants' attorneys during the personal interview at the USPTO on July 8, 2003 are gratefully acknowledged. During the interview, applicants' attorneys took the opportunity to explain in details of the present invention.

The present invention is directed to a pharmaceutical composition comprising a therapeutically-active compound (having low aqueous solubility and substantial protein binding affinity) and a plasma protein in controlled aggregation state wherein greater than about 98% of the therapeutically-active compound is non-covalently bound to the plasma protein in a water-soluble product suitable for parenteral administration.

Applicants acknowledged Examiners' statement that the cited Satoh reference was no longer prior art against the present application (because Satoh only teaches suspension but fails to teach or suggest a parenteral formulation). Applicants also acknowledged Examiners' willingness to consider the patentability of product claims, product-by-process claims, as well as the process claims in the present invention. Examiners discussed proposed amendment with respect to the terms of "controlled aggregation state" and "substantial binding affinity to plasma proteins."

Per Examiners' discussion and suggestions, Applicants respectfully submit herewith the present claim amendment. Specifically, new claim 141 is submitted which has incorporated many of the Examiners' suggestions. Claim 141 is a substitute for claim 95 (now canceled). New claims 141-181 depend on claim 96 and further incorporate limitations such as pairs of therapeutically-active compound and plasma protein. Claim 181 is a product-by-process claim.

#### **Claim Rejections - 35 U.S.C. § 102(b)**

Claim 95 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Satoh et al (EPO 0326618). After a detail explanation of the present invention, Examiners agreed (and applicants' attorneys acknowledged) that Satoh fails to teach or suggest a parenteral

solution. New claim 141 is introduced to substitute claim 95 (now canceled) and recites a parenteral composition. Accordingly, the claim rejection under 35 U.S.C. § 102(b) should be overcome.

### **Claim Rejection - 35 U.S.C. § 112**

Claim 95 stands rejected under 35 U.S.C. § 112, second paragraph as failing to particularly point out and distinctly claim the subject matter.

During the July 8, 2003 interview, Examiners discussed with applicants' attorneys proposed claim terms relating "a substantial binding affinity to plasma protein" and "controlled aggregation state." New claim 141 is introduced to substitute claim 95 (now canceled) and recites a parenteral composition. New claim 141 has incorporated many of the Examiners' suggestions and is believed to be novel and non-obvious.

Specifically, applicants have clarified the claim term for "a substantial binding affinity to plasma proteins." Claim 141 recites that the plasma protein is in a "controlled aggregation state" which the present specification provides an enabling disclosure to teach one skilled in the art to make and use of the invention (see, for example, page 7, lines 1-9). Applicants respectfully submit that the present inventors first invented and coined the term "controlled aggregation state" which indicates a state where a plasma protein is having the high binding activity towards a therapeutically-active compound.

Dependent claims 142-181 further incorporate limitations of claim 141. Majority of these dependent claims recite specific therapeutically-active compound with plasma protein including paclitaxel, amphotericin B, camptothecin, carbamazepine, cyclosporin A, propofol with plasma proteins such as human serum albumin, gamma globulin and recombinant proteins. These specific therapeutically-active compound/plasma protein pairs are fully supported in the specification (also pages 16-26, example II.1 to II.35) (also, see our June 18, 2002 Amendment, pages 9-10). No new matter is introduced.

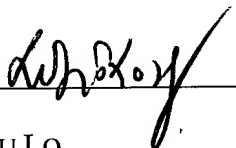
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**CONCLUSION**

In view of the foregoing remarks, Applicants respectfully submit that all the rejections should be withdrawn. All claims are believed in conditions for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at (212) 908-6018.

RESPECTFULLY SUBMITTED  
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